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NCIC HPV
Sent by: Mary-Beth Weaver

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To: NCIC HPV, moran.matthew@epa.gov
cc:
cc:
Subject: Environmental Defense comments on dithiophosphate alkyl esters category

Richard_Denison@environmentaldefense.org on 03/26/2003 10:09:03 AM

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Subject: Environmental Defense comments on dithiophosphate alkyl esters category

(Submitted via Internet 3/26/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and sarah_loftus@americanchemistry.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the proposed dithiophosphate alkyl esters cateyory.

The American Chemistry Council Petroleum Additives Panel's Health, Environmental and Regulatory Task Group (HERTG), in response to the EPA High Production Volume Challenge Program, has submitted a Robust Summary/Test Plan for nine dithiophosphate alkyl esters and proposed that they be considered as a category. Examination of the chemical structures of these nine chemicals indicates that they are quite similar and should have similar chemical/physical properties. Therefore, they would be expected to have similar fates in the environment and to exert similar toxicity. Thus, we agree that these nine chemicals should be considered together as a category.

According to the letter of submission and Test Plan, members of this proposed category are synthesized in closed systems and used on site to synthesize petroleum lubricant additives. Based on this and other background information presented in the Robust Summary/Test Plan submitted for this category, there appears to be limited potential for occupational exposure to these chemicals. Also, since they are apparently produced and used exclusively on-site, there is likely little potential for exposure of the environment or the general population. Should they be released into the environment, these chemicals have low acute toxicity, are non-volatile and have very limited water solubility. This may explain why these chemicals have not yet been subject to extensive environmental or toxicological testing and there are few or no data to support an assessment of environmental or human health risks.

While we are not calling for additional animal testing given the corrosivity of these chemicals, we consider the present Robust Summary/Test Plan inadequate. As presently drafted, the Test Plan goes to great lengths to explain how data addressing each of the SIDS elements is generated and how results of the tests, if they were conducted, would be interpreted. Neither the Robust Summary nor the Test Plan, however, provides any of the required data. We see no need for the instruction included in the submissions on such topics as Ames Tests or LD50 or how to do oral, inhalation and dermal toxicity studies. What is needed are the data generated by such studies for the compounds in question. If there are no such data, this fact needs to be clearly stated, along with what the

sponsor proposes to do to provide the data.

The Robust Summary submitted for this category consists of summaries of only two studies, both of which were very poorly conducted. These studies were not conducted under GLP. Neither study listed the purity of the chemical. In each case a single dose was used. The skin was abraded in the dermal study. And finally, most importantly, neither of these studies used chemicals that are members of this proposed category; rather, they used zinc salts of dithiophosphate alkyl esters, not the dithiophosphate alkyl esters themselves.

Other comments:
1. A great deal of attention is paid to the fact that chemicals in this category do not leave the site of synthesis, but are converted to zinc salts that are used in lubricants. However, virtually one hundred percent of the zinc salts do leave the plant where they are synthesized. There are no data to indicate to what extent the zinc salts disassociate to release the original compounds into the environment. These data should be included. Further, the accompanying Test Plan for the zinc salts proposed category states that these compounds degrade at temperatures above 120 degrees C. This raises a question not addressed in either Test Plan: what do the zinc salts degrade into? If the zinc salts degrade to the dithiophosphate alkyl esters, then there is significant potential for release of the latter compounds into the environment and more extensive data should be generated to address the required SIDS elements. If the zinc salts are degraded to some other known product, that product should be described. If the degradation products are unknown, they should be determined and that information provided.
2. Page 11, last paragraph: It is stated that CAS # 84605-28-7 is both the most soluble and insoluble member of the category. Which is it?
3. Page 13, Acute oral and dermal toxicity: It is stated that there are literature citations for dermal and oral LD50s. These data are not referenced, however, and are not described in the Robust Summary. This oversiqht should be corrected.
4. Page 14, section 4.3.2.3: It is stated that acute mammalian toxicity tests are available for a lower molecular weight analog. The analog is not identified, no reference is provided, and no data are presented in the Robust Summary. This oversight should be corrected.
5. 'Tables 4 through 6: None of these data are for chemicals actually in this proposed category. It is proposed that the requisite data will be provided by bridging from the zinc salts. Because the zinc salts are a complex of two molecules of the dithiophosphate alkyl esters, and we have no information as to the degree to which the salts disassociate, we have no way of knowing if the proposed bridging of data is appropriate. This oversight should be corrected or a better explanation provided.
6. Table 7: We do not propose animal testing in this case, given the corrosivity of these chemicals, but there is no reason genetic toxicity studies (could not be conducted for each of the compounds in this category.
7. Table 8 and corresponding text: HERTG asserts, without providing any data, that these compounds are too corrosive to test in animals. If that is the case, we support the proposal, but chemical evidence, e.g., pKa, literature references, etc., needs to be presented in support of this statement.
8. The summary table for the Test Plan indicates "Read Across" will be used to generate data for a number of the desired SIDS elements. While we are not advocating animal testing, data using methods or models not requiring animals should be generated for each of these endpoints for each of these compounds.
9. The summary table for this Test Plan indicates "Read Across" will be used to qenerate biodegradation data for each of the compounds in this proposed category. If, as the table suggests, no measured data are to be

generated for any of these compounds, however, what data are to be the basis for "Read Across"?

In summnry, for the reasons listed above, this is not an acceptable Robust Summary/Test Plan.

[Note: EPA personnel responsible for posting this document should be aware some pages will not print. Further, when one tries to print them they are lost from the text and can be regained only by reloading the entire document.]

Thank you for this opportunity to comment.

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